

**REMARKS**

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 1-33 are in this case. Claims 1-17, and 29-33 have been withdrawn from consideration. Claims 18 and 20-28 have been rejected. Claims 18 and 22 have now been amended. Claim 19 has been previously cancelled.

***35 U.S.C. §112, First paragraph Rejections***

The Examiner has rejected claims 18, 23 and 25-27 under 35 U.S.C. §112, first paragraph, for lack of enablement. The Examiner's rejections are respectfully traversed. Claims 18 and 22 have now been amended.

The Examiner has stated that the specification, while being enabling for repopulating a devitalized acellular three dimensional scaffold with pluripotent stem cells or progenitor cells or differentiated cells derived from the same tissue source as the scaffold, does not reasonably provide enablement for repopulating the scaffold with any differentiated cell type, other than those derived from the same tissue source as the scaffold, and as such does not enable any person skilled in the art to make and/or use the invention commensurate in scope with claims 18, 23 and 25-27. The Examiner has stated that the specification fails to define the phrase "homologous differentiated cell", and therefore the claim is not limited to differentiated cells derived from the same tissue source as the scaffold. The Examiner has further rejected claims 18 and 20-28 as containing new matter, which was not described in the specification at the time the application was filed, stating that the phrases "homologous progenitor cells" and "homologous differentiated cells" lack literal support in the specification as filed.

In order to further expedite this case, independent claim 18 and dependent claim 22 have now been amended to recite:

18. A method of generating an artificial micro-organ comprising:

(a) providing devitalized, acellular, tissue-derived three dimensional scaffold, said acellular three dimensional scaffold being of dimensions selected such that when populated with cells, said cells positionable deepest within said scaffold are at least about 100 micrometers and not more

than about 225 micrometers away from said cells positioned at a nearest surface exposed to a source of gas and nutrients formed on said scaffold; and

(b) seeding said acellular three dimensional scaffold with stem cells, progenitor cells or differentiated cells, wherein said differentiated cells are of the same tissue from which the scaffold was generated, and

(c) providing conditions for cell growth and proliferation.

22. The method of claim 18, wherein said cells seeded on said acellular three dimensional scaffold are a mixed population of cells including stem cells, progenitor cells and differentiated cells, wherein said differentiated cells are of the same tissue from which the scaffold was generated.

Claim 28 has now been amended to recite the limitation of progenitor cells derived from the same tissue source as said microorgan:

28. The method of claim 25, wherein said progenitor cells are progenitor cells derived from the same tissue source as said micro-organ.

Thus, now amended claims 18, 22 and 28, and all claims dependent therefrom, read on scaffolds comprising acellular, tissue-derived micro organs seeded with stem, progenitor or differentiated cells, wherein the differentiated cells are of the same tissue from which the scaffold was generated, or wherein the progenitor cells are from the same tissue source as the microorgan. Support for such amendments is found throughout the instant specification, for example, in claims 19 (now cancelled), 22 and 28, and page 24, lines 17-19:

“...such a scaffold when seeded with stem cells (adult or embryonic) and optionally differentiated cells can be used to generate a micro-organ like three dimensional tissue structure.”

And page 41, lines 9-11:

“Taken together, these results demonstrate the ability of micro organs to support the growth and proliferation of embryonic and adult derived stem cells, of homologous and non-homologous tissue and species origin.”

In view of the abovementioned arguments and amendments, Applicant believes to have overcome the 112, first paragraph rejections.

***35 U.S.C. §112, Second paragraph Rejections***

The Examiner has rejected claims 18, and 20-28 under 35 U.S.C. §112, second paragraph, for lack of failing to point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner's rejections are respectfully traversed. Claims 18, 22 and 28 have now been amended.

The Examiner has stated that the term "homologous differentiated cells" is not defined by the specification or the claims, and that it is not clear whether it is to be interpreted as a differentiated cell of the same tissue type as the scaffold in the same species, or a homologous tissue type from a different species of organism.

As detailed hereinabove, Claims 18 and 22 have now been amended so that the term "homologous" has been replaced by the limitation of the differentiated cells being of the same tissue from which the scaffold was generated, further defining the tissue origin of the differentiated cells use for repopulation of the acellular, tissue-derived three dimensional scaffold taught therein.

In view of the abovementioned arguments and amendments, Applicant believes to have overcome the 112, second paragraph rejections.

In view of the above amendments and remarks it is respectfully submitted that amended claims 18 and 22, and all claims which directly or indirectly depend therefrom are now in condition for allowance. Prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

*Martin Q. Moynihan*

Martin Moynihan  
Registration Number 40,338

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Martin Moynihan  
PRTSI, Inc.  
P.O. Box 16446  
Arlington, VA 22215

Tel: (703) 598-7851 Fax: (703) 415-4864